PASCAL®

DYNAMIC CONTOUR TONOMETER

www.pascal-tonometer.com

The Precision Tonometer.

ZIEMER OPHTHALMIC SYSTEMS OF SWITZERLAND

PASCAL® DYNAMIC CONTOUR TONOMETER

The New Device for Ocular Precision Tonometry:

PASCAL's main components:

1. SensorTip
2. Cantilever (spring-loaded arm)
3. Mounting bracket
4. Control switch ("Blue Knob")
5. LCD Display
6. Wireless printer (optional)

The PASCAL® Dynamic Contour Tonometer is a third-generation, digital, contact tonometer for ophthalmological applications. The slitlamp-mounted device furnishes a numeric output of intra-ocular pressure (IOP) and of ocular pulse amplitude (OPA) upon touching the cornea for a few seconds. It measures pulsatile IOP directly and continuously (dynamically).

Features

- Slitlamp-mounted –
  same easy operation as the familiar applanation tonometer
- Disposable tip cover prevents contamination and potential infection –
  safe and convenient
- Direct measurement of pressure –
  no systematic errors from force-to-pressure conversion
- Numerical display of result – avoids operator bias and reading errors
- Self-calibrating – no calibration required
- Battery operated – no cabling
- Transparent tip provides for visual control of corneal interface
- All functions are accessed with the unique Blue Knob –
  easy, single button operation

Clinical Benefits

- ❑ Unlike applanation tonometers, which are influenced by corneal thickness and other characteristics of the cornea and hence may produce misleading estimates of IOP, a contour tonometer provides an **accurate direct measurement of true IOP** which is independent of inter-individual variations in corneal properties.
- ❑ IOP measurement works correctly even on post-LASIK eyes.
- ❑ PASCAL detects and accurately measures the dynamic pulsatile fluctuations in IOP and thus permits a more detailed assessment of the **pressure *range*** to which the eye is subjected due to pulsatile ocular blood flow.
- ❑ No fluoresceïn staining is required for the measurement.
- ❑ Convenient documentation with optional wireless printer: Prints all the values shown on the LCD display and the actual IOP curve.

"In summary, (we) found IOP measurements taken with the new DCT (Dynamic Contour Tonometer) to have an excellent concordance with measurements obtained by the GAT (Goldmann Applanation Tonometer). In the subjects studied, IOP measurements with the DCT did not depend on corneal thickness, corneal curvature, or axial length." (…)

"DCT may offer some clinically relevant advantages over conventional Goldmann-type applanation tonometers for screening and management of patients with suspected or known glaucoma."

(Comparison of Dynamic Contour Tonometry with Goldmann Applanation Tonometry. Kaufmann C, Bachmann LM, Thiel MA; IOVS 2004, Vol. 45, No. 9, 3118 – 3121).

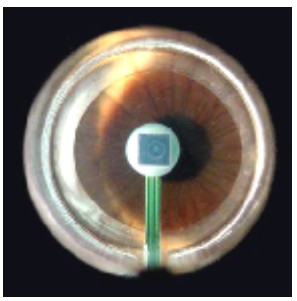
Ziemer Ophthalmic Systems

© 2005 Ziemer Ophthalmic Systems AG

www.pascal-tonometer.com

How the PASCAL Tonometer works

SensorTip with contour-matched contact surface



Contact area of cornea as seen through slit lamp microscope

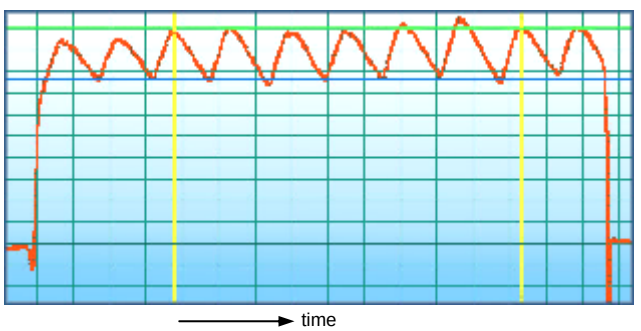
PASCAL is always ready for operation: just swivel it into place before the patient's eye, activate it with a single touch of the Blue Knob, advance it to touch the patient's eye, pull back after a few seconds, and immediately see the numerical result, precise and unambiguous, on the unit's illuminated LCD display.

When the PASCAL SensorTip touches the corneal surface, a solid-state, piezoresistive pressure sensor, built into the center of the contoured, concave tip surface, directly measures IOP. The contour surface has been calculated to generate minimum distortion of the cornea (**contour matching**) and hence minimize tension forces within the cornea.

The device can be mounted on any slitlamp, and is advanced towards the patient's eye by using the slitlamp's joystick. The SensorTip is mounted on a spring-loaded Cantilever which provides a constant appositional force.

The pressure detected by the sensor is digitized and stored in the device's memory. A built-in microprocessor determines the intra-ocular pressure (IOP) and its pulsatile fluctuations (ocular pulse amplitude, OPA) caused by cardiac activity. IOP and OPA are displayed as numeric values on an LCD display. The part of the tip touching the eye is protected by a single-use disposable cover, the "SensorCap". The unit is battery-operated.

This is what the PASCAL tonometer measures:



Original ocular pulse curve, detected in real-time by PASCAL (100Hz sampling frequency).

Yellow cursors: range of optimum curve quality as determined by software.

Blue line: level of mean diastolic IOP. The pressure level corresponding to this line is displayed as **IOP**.

Green line: level of mean systolic IOP. The difference between green and blue line is displayed as **OPA**.

Note: This curve, representing raw data as collected by the PASCAL device, is only visible if an optional printer or PC is connected.

…and this is the result presented on the LCD:

(above:) result displayed immediately after measurement.

(below:) result recalled from list of stored results.

IOP (P; mmHg): average of pulse minima (3 – 6 minima are detected in a curve range optimized for data quality).

OPA (A; mmHg): difference between mean minimum and mean maximum of pulse curve.

Q: Quality of data and of result. 1 is optimum; 2 and 3 are acceptable; 4 and 5 are unacceptable and should be discarded, and measurement repeated.

#nnn (displayed only in list of stored results): measurement identification number.

H (displayed only in list of stored results): cardiac pulse rate (beats/min).

Sales and Service: Ziemer Ophthalmic Systems AG, CH-2562 Port, Switzerland phone: +41 32 332 7050 vision@ziemer-ophthalmics.com

Manufactured by: Swiss Microtechnology AG, a Ziemer Ophthalmics Group Company phone: +41 32 332 7080 vision@smtag.ch

Technical Data

- Class IIa medical device. CE-marked. FDA 510(k) cleared
- Device mounts on tonometer bracket or accessory footplate of slitlamp
- Dimensions: Housing: 170 mm (H) x 88 mm (W) x 40 mm (D)
- Weight: ca. 210 grams
- Display of results: backlit LCD 58 x 24 mm (2.2' by 1')
- Detection range: IOP 5 – 200 mmHg; OPA >1.0 mmHg (numerical precision ±0.2 mmHg)
- Analog/digital conversion: 100 Hz sampling rate; 12 bit resolution
- Recording time: ca. 3 secs up to 180 secs
- Calibration: self-calibrating; automatic compensation of atmospheric pressure. Optional Test Kit is available for checking tonometer calibration and performance
- Appositional force: 1 gram
- SensorTip diameter: 7 mm (pressure sensor: 1.2 mm)
- Contact surface: concave, shaped to match corneal contour
- Cleaning/sterilization: SensorTip is protected from direct eye contact by sterile, single-use SensorCap covers
- Power: battery-operated (3V battery pack)

Product Information CE 0297

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

- Manufacturer: SMT Swiss Microtechnology AG, CH-2562 Port, Switzerland (a Ziemer Ophthalmic Systems Group Company)
- Sales & Service: Ziemer Ophthalmic Systems AG, CH-2562 Port (Switzerland) and its network of established ophthalmic equipment distributors. www.pascal-tonometer.com
- Availability: Europe: CE-marked. USA: FDA 510(k) cleared. For other countries, availability may be restricted due to local registration requirements; please contact Ziemer Ophthalmics for details.
- Configuration: single unit, completely assembled (self-installed by user) screws onto available tonometer bracket, or fits onto pivotal axis of most Haag-Streit-type slitlamps. Adapter Kits for other slitlamps (Zeiss, Rodenstock) are available.
  SensorTip may be detached for cleaning.
  Basic configuration includes attachment kit for mounting the unit on swiveling bracket of slitlamp (swiveling bracket not supplied), two battery packs, and initial supply of sterile, single-use SensorCaps. With aluminum carrying case and operating manual.
- Accessories, Consumables:
  - Slitlamp adapter kit (required for different types of slitlamp attachment; please check with your distributor).
  - Additional detachable SensorTips.
  - Wireless interface for connecting to an optional printer, or to a Personal Computer.
  - Test Kit for checking tonometer calibration and performance.
  - Sterile SensorCap disposable tip covers in AppliPack packaging (package of 240 ea).
  - Disposable Battery Packs (standard), or Rechargeable Battery Pack with battery charger (optional).
- Service: Regular Maintenance and Repair Service is available from the manufacturer and from local certified Service Centers (please contact your local distributor or consult the PASCAL Tonometer website for address information). Regular performance checks are recommended and may be performed by the user by means of the optional Test Kit, or by service centers and distributors. If the test reveals a need for re-calibration, the device must be sent to a Service Center for maintenance.
  Convenient Maintenance and Service Contracts are available.
- Warranty: The PASCAL Dynamic Contour Tonometer comes with a 12-month limited warranty on parts and workmanship. Please consult Ziemer Ophthalmic Systems' Warranty Terms for details.

Ordering Information

Part Nbr.	**System**
311.001.00x	PASCAL® Dynamic Contour Tonometer System, includes: Main Unit, one SensorTip, carrying case, and the following starter set of consumables: SensorCaps, 24 ea., in AppliPack packaging, Battery Packs (disposable; 2 ea.)
311.011.00x	PASCAL® Dynamic Contour Tonometer System as described above, but with wireless printer interface
	Consumables
311.701.201	SensorCaps, 240 sterile, disposable tip covers, in AppliPack packaging
311.751.002	Replacement Batteries (not rechargeable); package of 5
	Printer
311.660.001	Wireless portable thermal printer, battery-operated, uses 58mm roll paper
311.660.010	Thermal roll paper, 58mm width

Accessories	
311.761.001	Rechargeable Battery Kit: Battery charger and 2 rechargeable batteries
311.761.005	Rechargeable Batteries, package of 2
311.620.001	Test Kit for checking calibration and system performance
311.510.002	SensorTip
311.510.003	SensorTips, package of 3
311.640.005	Adapter kit for mounting the PASCAL Main Unit on Haag-Streit-type slitlamps using central base post
311.640.006	Base plate with fixation pins and locking key; for mounting PASCAL on bottom
311.640.007	Footplate A; standard
311.640.008	Footplate B; special for “non-HS”-slitlamps
311.951.101	PASCAL User Manual on CDROM (in English, German, French, Italian, and Spanish)
311.951.201	PASCAL Quick Reference Sheet in English, also available in German, French, Italian, and Spanish

Actual product characteristics, specifications, and prices are subject to change.